

REMARKS

Claims 1, 2, 4-7, 9, 10, 12-16, 18 and 19 are in the application and are presented for examination. Claims 3, 8, 11 and 17 have been cancelled. The amendment to Claim 1 is supported by the disclosure at page 7, lines 9-12, of the specification as filed. No new matter has been added.

As required by the Examiner, certified copies of the foreign priority applications filed in the PCT application are submitted herewith to obtain benefit of the filing dates of the applications.

OBJECTIONS TO THE SPECIFICATION

As requested by the Examiner, headings designating different sections have been inserted into the specification by amendment. The headings include, Background of the Invention; Field of the Invention; Description of the Related Art; Summary of the Invention; Brief Description of the Drawings; and Detailed Description of the Invention.

REJECTION UNDER 35 U.S.C. 112, FIRST PARAGRAPH

The Examiner has rejected Claims 18 and 19, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Applicants respectfully traverse this rejection for the following reasons.

Claims 18 and 19 are directed to processes for encouraging growth of living tissue by using the substrate of Claim 1 that has at least a portion of its surface coated with living cells. Support for Claims 18 and 19 is clearly found at page 4, lines 1-9 of the specification as filed, and at page 3, lines 4-33. It is stated that water soluble glass acts as a support or matrix for cell growth and is, therefore, useful in tissue engineering. It is further stated that the water-soluble glass present in the graft acts as a cell support matrix and will function as such in vivo. As a result, the graft can be used directly in vivo to provide a temporary biodegradable scaffold which will encourage ingrowth of surrounding tissues.

Applicants contend that the disclosure in the specification supports the content of Claims 18 and 19. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of Claims 18 and 19, under 35 U.S.C. 112, first paragraph.

REJECTIONS UNDER 35 U.S.C. 112, SECOND PARAGRAPH

The Examiner has rejected Claims 11, 18 and 19, under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection for the following reasons.

The rejection of Claim 11 is no longer on point in view of Applicant's cancellation of Claim 11.

Claim 18 describes a process for encouraging growth of living tissue that entails providing a substrate comprising a water-soluble glass matrix having at least a portion of the surface coated with living cells. The substrate serves as a temporary biodegradable scaffold which will encourage ingrowth of surrounding tissues.

Applicant contends there is nothing confusing and/or unclear regarding the process of Claim 18. The process requires the single step of providing the substrate. Accordingly, Applicants respectfully request the Examiner withdraw the rejection of Claim 18, under 35 U.S.C. 112, second paragraph.

Claim 19 has been amended to remove any unclarity regarding antecedent basis. Claim 19 describes an operational process step that is supported by the disclosure at page 6, lines 4-9, of the specification as filed. It is therefore requested that the Examiner withdraw the rejection of Claim 19, under 35 U.S.C. 112, second paragraph.

REJECTION UNDER 35 U.S.C. 103 (a)

Claims 1, 2, 4-7, 9-12, 18 and 19 have been rejected, under 35 U.S.C. 103 (a), as being patentable over the article by Burnie et al. entitled "Controlled Release Glasses (C.R.G.) for

Biomedical Uses” (herein Burnie et al.) in view of WO 98/54104 to Gilchrist et al., and if necessary, in further view of U.S. Patent No. 4,748, 121 (herein the ‘121 patent.) Applicants respectfully traverse this rejection for the following reasons.

The Burnie et al. article discloses, in the paragraph bridging pages 244 and 245, the use of water-soluble glass substrate in monolayer cell culture. However, the water-soluble glass substrate is not comprised of the same material as that of Applicants’ claimed invention. As recognized by the Examiner, the water-soluble glass substrate of Burnie et al. does not contain a boron-containing compound. The claimed invention of Applicants specified further that the water-soluble glass substrate must contain, alternatively to the boron-containing compound, a metallic ion.

In this respect, the Examiner has concluded that the water-soluble glass substrate of Burnie et al. contains sodium, and as such, would be similar to Applicants’ claimed invention. This was not the intended meaning of Applicants’ invention, and to clarify the invention, Claim 1 has been hereby amended. The amendment to Claim 1 makes clear that the metallic ion contained in Applicants’ water-soluble glass substrate is a metallic ion that confers either antimicrobial protection or enhanced cell growth, or both. This is disclosed at page 7, lines 9-16 of the present application. Examples of such metallic ions included within the claimed invention are said to be silver, copper, magnesium, zinc, iron, cobalt, molybdenum, chromium, manganese, cerium, selenium, individually or in combination. It should be noted that sodium is not mentioned as a suitable metallic ion. The use of sodium in the water-soluble glass substrate is in connection with a completely different purpose. As explained on page 6, line 25 – page 7, line 2, of the present application, sodium containing oxides are used as glass modifiers that are non-toxic, and that influence the rate at which the water-soluble glass dissolves in fluids. The present Claim 1, as hereby amended, clarifies the meaning of the metallic ions in the water-soluble glass, and thus does not include sodium as an ion within the metallic ions of Claim 1.

The WO/ 98/54104 has been described as showing that water-soluble glass fibers may contain boron and/or silver ions. There is not however, any disclosure or suggestion that the materials of WO 98/54104 would be suitable for use as cell culture growth substrates.

The '121 patent to Beaver et al. discloses a glass for immobilizing cells. The glass differs from the water-soluble glass of Applicants' invention, and accordingly is not related to the present claimed invention. The glass of the '121 patent is comprised of 35-60 weight percent  $B_2O_3$  and about 35-60 weight percent silica.

From the description of the Burnie et al. article, WO 98/54104, and the '121 patent, Applicants contend there is neither any disclosure, or suggestion, of the water-soluble glass cell culture growth substrate of Applicants' invention. Furthermore, there is nothing to suggest that one of ordinary skill in the art would have been motivated to combine any or all of the cited references, to achieve Applicants' claimed invention.

In further regard to the unexpected and surprising results of the presently claimed invention, Applicants call attention to the following. The metallic ions of Applicants' presently claimed invention, as generally exemplified on page 7, lines 9-17, of the present application, are generally considered to be toxic to the human body. However, addition of the metallic ions to the water-soluble glass substrate of the present invention stimulated, rather than disrupted, cell growth. This is shown by the results of the examples at pages 35 to 40, of the present application as filed. This stimulatory effect was surprising and unexpected, and was contrary to the commonly held views of those skilled in the art of formation of water-soluble glass.

The Burnie et al. article discloses a controlled release glass that includes sodium. As shown in the present application, at page 6, line 25 to page 7, line 2, the sodium ions are commonly added to water-soluble glass compositions to control the rate of dissolution of the glass.

In view of the foregoing, Applicants contend that Claims 1, 2, 4-7, 9, 10, 12, 18, and 19 are patentable over Burnie et al. in view of WO 98/54104 and if necessary in further view of U.S. Patent No. 4,748,121. Accordingly, Applicants respectfully request the Examiner to withdraw the rejection of Claims 1, 2, 4-7, 9, 10, 12, 18, and 19, under 35 U.S.C. 103 (a).

REJECTION OF CLAIMS 13-16 UNDER 35 U.S.C. 103 (a)

The Examiner has rejected Claims 13-16, under 35 U.S.C. 103 (a) as being unpatentable over the Burnie et al. article, WO 98/54104, and U.S. Patent No. 4,748,121, as applied to Claims 1, 2, 4-7, 9, 10, 12, 18, and 19, and further in view of U.S. Patent No. 5,811,302 to Ducheyne et al. (herein the '302 patent.) Applicants respectfully traverse this rejection for the following reasons.

The '302 patent describes, at column 4, lines 1-10, the sintering of a porous glass substrate, that permit the in vitro formation of bone tissue when exposed to a tissue culture medium and inoculated with cells. However, even if one were to combine the '302 patent with any or all of the earlier described references, one would still not achieve Applicants' presently claimed invention. None of the references cited herein disclose or suggest the Applicants' presently claimed water-soluble cell culture growth substrate. Nor does any combination of the cited references disclose or suggest the presently claimed water-soluble cell culture growth substrate.

In view of the above, Applicants respectfully request the Examiner to withdraw the rejection of Claims 13-16, under 35 U.S.C. 103 (a), as being unpatentable over Burnie et al., in view of WO 98/54104, U.S. Patent No. 4,748,121, and U.S. Patent No. 5,811,302.

CONCLUSION

Applicants believe the application is in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the rejections of Claims 1, 2, 4-7, 9, 10, 12-16, 18, and 19.

Applicants submit that all claims in the present application are patentable, and respectfully request the Examiner to pass the application to issue.

Respectfully submitted,



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